

SEP 11 2007

Serial No. 10/750,934
Docket No. 0101.00

The following listing of claims will replace all prior versions and listings of claims in the application:

Claims:

1. (Currently Amended) A pharmaceutical formulation for pulmonary administration as a powder, the pharmaceutical formulation comprising:
~~particulates comprising consisting essentially of an active agent particle particles in a phospholipid lipid matrix, the active agent having a solubility in water of less than 1.0 mg/ml; wherein the active agent particles are dispersed throughout the phospholipid matrix; and~~
~~wherein at least 90% of the active agent particles in the pharmaceutical formulation have a geometric diameter less than 3 μm and wherein the particulates have a mass median diameter less than 10 20 μm and a bulk density of less than about 0.5 g/cm³.~~
2. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein the particulates have a mass median aerodynamic diameter less than 10 μm about 2.6 μm .
- 3 (Currently Amended). A pharmaceutical formulation according to claim 1 wherein the particulates have a mass median diameter less than 5 μm a formulation emitted dose is at least about 93 percent.
4. (Currently Amended). A pharmaceutical formulation according to claim 1 wherein at least 95% of the active agent particles have a geometric diameter less than 3 μm a formulation fine particle fraction of less than 3.3 μm is at least about 72 percent.
5. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein at least 50% of the active agent particles have a geometric diameter between 0.5 μm and 3 μm the formulation exhibits an Ostwald ripening as depicted in Fig 1.

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6. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein ~~at least 50% of the active agent particles have a geometric diameter between 1 µm and 3 µm the formulation provides for the delivery to the lung of a dose of at least about 5 mg in a single inhalation.~~

7. (Original) A pharmaceutical formulation according to claim 1 wherein the lipid matrix comprises one or more phospholipids.

8. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein the lipid matrix comprises one or more of dipalmitoylphosphatidylcholine, ~~distearylphosphatidylcholine distearoylphosphatidylcholine,~~ diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol, short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines, long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols, and long-chain saturated phosphatidylinositols.

9. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are hollow.

10. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are porous.

11. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are hollow and porous.

12. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein ~~the pharmaceutical formulation has a bulk density of less than 0.5 g/cm³ the active agent comprises tobramycin.~~

13. (Original) A pharmaceutical formulation according to claim 1 wherein the pharmaceutical formulation has a bulk density of less than 0.3 g/cm³.

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14. (Original) A pharmaceutical formulation according to claim 1 wherein the pharmaceutical formulation has a bulk density of less than 0.2 g/cm³.
15. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are in dry powder form for aerosolization in a dry powder inhaler.
16. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are suspended in a propellant for aerosolization in a metered dose inhaler.
17. (Original) A pharmaceutical formulation according to claim 1 wherein the particulates are suspended within a liquid for aerosolization in a nebulizer.
18. (Original) A pharmaceutical formulation according to claim 1 wherein the active agent particle is crystalline.
19. (Original) A pharmaceutical formulation according to claim 1 wherein the particulate further comprises a polyvalent cation.
20. (Currently Amended) A pharmaceutical formulation according to claim 1 wherein the active agent has a solubility in water of less than [[0.1]] 1.0 mg/ml.
21. (Currently Amended). A pharmaceutical formulation according to claim 1 wherein the particulates are formed by spray drying with a blowing agent.
22. (Original) A pharmaceutical formulation according to claim 1 wherein the insoluble active agent comprises an antimycotic agent.
- 23 – 37 (Withdrawn).
38. (Currently Amended) A pharmaceutical formulation for pulmonary administration,

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the pharmaceutical formulation comprising:

particulates comprising an consisting essentially of active agent amphotericin-B particles in a lipid matrix comprising a phospholipid, the active agent having a solubility in water of less than 1.0 mg/ml and wherein the active agent particles are dispersed throughout the phospholipid matrix; and

wherein at least 90% of the amphotericin-B active agent particles in the pharmaceutical formulation have a geometric diameter less than 3 μm and wherein the particulates are hollow and/or porous, and have a mass median diameter less than 20 μm , a bulk density of less than about 0.5 g/cm³ and a mass median aerodynamic diameter less than about 2.6 μm .

39. (Currently Amended) A pharmaceutical formulation according to claim 38 wherein the particulates have a mass median diameter less than 10 μm the formulation provides for the delivery to the lung of a dose of at least about 5 mg in a single inhalation.

40. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates have a mass median diameter less than 5 μm .

41. (Currently Amended) A pharmaceutical formulation according to claim 38 wherein at least some of the particulates comprise a plurality of amphotericin-B particles in a lipid matrix a formulation fine particle fraction of less than 3.3 μm is at least about 72 percent.

42. (Currently Amended) A pharmaceutical formulation according to claim 38 wherein the amphotericin-B particles are crystalline the formulation provides for the delivery to the lung of a dose of at least about 5 mg in a single inhalation.

43. (Cancelled).

44. (Currently Amended) A pharmaceutical formulation according to claim 38 wherein the lipid matrix comprises one or more of dipalmitoylphosphatidylcholine,

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distearylphosphatidylcholine distearoylphosphatidylcholine,
diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol,
short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines,
long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols,
and long-chain saturated phosphatidylinositols.

45-46 (Cancelled)

47. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates have a bulk density less than 0.3 g/cm³.

48. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates have a bulk density less than 0.2 g/cm³.

49. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates are in dry powder form for aerosolization in a dry powder inhaler.

50. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates are suspended in a propellant for aerosolization in a metered dose inhaler.

51. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates are suspended within a liquid for aerosolization in a nebulizer.

52. (Original) A pharmaceutical formulation according to claim 38 wherein the particulates further comprise a polyvalent cation.

53. (Currently Amended) A pharmaceutical formulation according to claim 38 wherein the particulates are formed by spray drying with a blowing agent.

54. (Currently Amended) A pharmaceutical formulation for pulmonary administration, the pharmaceutical formulation comprising:

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particulates comprising an amphotericin B particle in a lipid matrix comprising a phospholipid wherein the amphotericin B particles have a solubility in water of less than 1.0 mg/ml, and are dispersed throughout the phospholipid matrix, and;

wherein the particulates are hollow and/or porous and wherein the particulates have a mass median diameter less than 20 μm , a bulk density of less than about 0.5 g/cm³ and a mass median aerodynamic diameter less than about 2.6 μm .

55. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates have a mass median diameter less than 10 μm .

56. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates have a mass median diameter less than 5 μm .

57. (Cancelled) A pharmaceutical formulation according to claim 54 wherein at least some of the particulates comprise a plurality of amphotericin B particles in a lipid matrix.

58. (Original) A pharmaceutical formulation according to claim 54 wherein the amphotericin B particles are crystalline.

59. (Cancelled) A pharmaceutical formulation according to claim 54 wherein the lipid matrix comprises one or more phospholipids.

60. (Currently Amended) A pharmaceutical formulation according to claim 54 wherein the lipid matrix comprises one or more of dipalmitoylphosphatidylcholine, distearylphosphatidylcholine distearylphosphatidylcholine, diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol, short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines, long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols, and long-chain saturated phosphatidylinositols.

61. (Cancelled)

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62. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates have a bulk density less than 0.3 g/cm³.

63. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates have a bulk density less than 0.2 g/cm³.

64. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates are in dry powder form for aerosolization in a dry powder inhaler.

65. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates are suspended in a propellant for aerosolization in a metered dose inhaler.

66. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates are suspended within a liquid for aerosolization in a nebulizer.

67. (Original) A pharmaceutical formulation according to claim 54 wherein the particulates further comprise a polyvalent cation.

68. (Currently Amended) A pharmaceutical formulation according to claim 54 wherein the particulates are formed by spray drying with a blowing agent.

69- 83 (Cancelled).

84 -102 (Withdrawn)

103. (New) A pharmaceutical formulation according to claim 1 wherein the active agent comprises ciprofloxacin.